Service Manual
for
BodyGuard 323, 545, & 575
Infusion pumps

CE 0344

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Introduction

This manual provides instructions for the service of BodyGuard infusion pump models 323, 545, and 575 and their software, and mechanical service for pole mount chargers. Sets are single use and are not serviceable.

The following requirements and conditions apply when performing service on BodyGuard products, failure to follow these instructions will invalidate warranty and creates unacceptable risk:

- Service of BodyGuard pumps, chargers and accessories may only be performed by CME authorized service personnel. Service can only be performed with the recommended equipment and CME approved parts.
- This manual is intended to support CME authorized service technicians performing service.
- Clinical personnel, patients, and other users are advised to return pumps to an authorized service center for service.
- Refer to operation manual for pump operation instructions, cautions and warnings.
- Refer to BodyComm operations manual for BodyComm operation instructions.
- Document service performed in accordance with service provider's prevailing procedures.

Warnings and Cautions

Warning: Warnings advise you of circumstances that could result in injury or death to the patient or operator. Read and understand this manual and the Operation's Manual taking note of all warnings before operating or performing service on the BodyGuard Infusion System.

Caution: Cautions advise you of circumstances that could result in damage to the device. Read and understand this manual and the Operation's Manual taking note of all cautions before operating or performing service on the BodyGuard Infusion System.

☞ **Note**: Indicates that the information that follows is additional important information or a tip that will help you when operating or performing service on the BodyGuard Infusion System.

Warnings

To avoid possible personal injury or loss of life, observe the following:

Read the entire Operation's Manual before using the pump, since the text includes important precautions.

The maximum volume that may be infused under SINGLE FAULT CONDITION is 0.1 ml.

Voltage present on internal components may cause severe shock or death upon contact. Disconnect the charger from AC power prior to opening the casing. Only authorized service personnel should open the pump cover.

Blown fuses could cause a fire hazard. Replace blown fuses on the charger only with fuses of the same type and rating (see fuse values on the charger PCB).

The equipment is not suitable for use in the presence of flammable anesthetic-air/oxygen/nitrous oxide mixture. Do not use the system in the presence of these gases.

Make sure the pump is attached securely to the charger, which is connected snugly to an IV pole.

A kinked or occluded IV line may impair the operation of the pump and the accuracy of the infusion. Before operation, verify that the IV line is not kinked or occluded.

The BodyGuard should be operated only with BodyGuard tubing sets. Use of administration sets other than manufacturer-produced BodyGuard tubing set may impair the operation of the pump and the accuracy of an infusion.

Drugs must not be administered to the epidural space unless the drugs are indicated for this purpose and are administered in accordance with the indications included in the manufacturer's package insert accompanying the drugs.

Epidural administration of drugs other than those indicated for epidural use could result in serious injury to the patient.

Any adjustments, maintenance, or repair of the uncovered pump may impair the operation of the BodyGuard Infusion System and/or the accuracy of the infusion. Only CME authorized technicians should perform any adjustments, maintenance, or repair of the uncovered pump. Any adjustments, maintenance, or repair of the uncovered pump while connected to the power should be avoided.

The BodyGuard Infusion System should be operated within a temperature range of 15°C (50°F) to 45°C (115°F) and at up to 85% humidity. Operating the pump at temperatures and/or humidity other than within this range may affect accuracy.

Unsafe operation may result from using improper accessories. Use only accessories and options designed for this system and supplied by manufacturer.

The BodyGuard tubing sets should not be use for blood, blood products or nitroglycerin administration.

Battery charging is enabled as long as the charger cord is connected to AC power and the pump is in the charger. Switching the pump off does not disconnect it from AC power. To disconnect from AC power, remove the charger cord from AC power. To disconnect pump from AC power, remove it from the charger.

Dropping the BodyGuard Infusion System could cause damage to components. If the pump is dropped, return the pump for inspection by qualified service personnel.

Use aseptic technique. Patient infection may result from the use of non-sterile components. Maintain sterility of all disposable components and do not re-use single use IV sets.

When operating the pump in PCA mode with a rate of 0.0 ml/hr there is a hazard of blood clot formation. Connect saline infusion in parallel to avoid this problem.

Do not operate the pump near high-energy radio-frequency emitting equipment, such as electro-surgical cauterizing equipment. False alarm signals may occur.

Watch your fingers / nails when opening and closing the pump door.

Cautions

To avoid possible damage to the equipment, observe the following:

Leaving the battery in a discharged state for a long period of time may damage the battery. Connect the pump to the AC power via the charger whenever possible to recharge the battery.

Do not store the pump with the battery fully depleted.

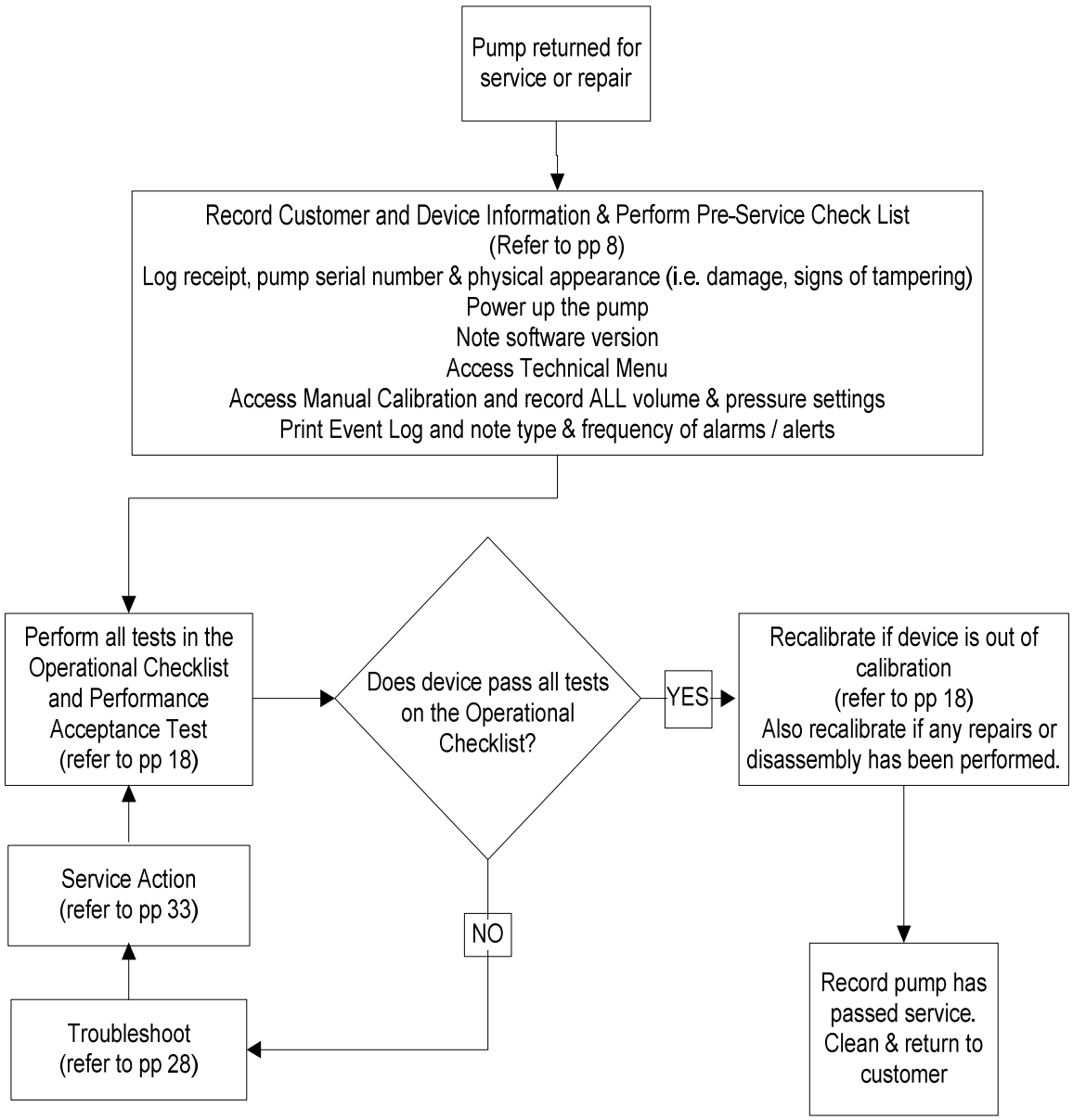
Xylene, acetone or similar solvents could cause damage to components. Do not clean the pump with these chemicals. Clean solution spills on the pump immediately. Use a damp cloth or sponge. A mild detergent may be used. Wipe thoroughly with a dry cloth.

Immersing the BodyGuard Infusion pump into liquid could cause damage to components. Do not immerse the pump into any type of liquid.

Battery damage could occur if left in a temperature warmer than 50^0C.

Service Process Diagram

The service operation is diagrammed below:


Pump returned for service or repair
Record Customer and Device Information & Perform Pre-Service Check List
(Refer to pp 8)
Log receipt, pump serial number & physical appearance (i.e. damage, signs of tampering)
Power up the pump
Note software version
Access Technical Menu
Access Manual Calibration and record ALL volume & pressure settings
Print Event Log and note type & frequency of alarms / alerts
Perform all tests in the Operational Checklist and Performance Acceptance Test
(refer to pp 18)
Does device pass all tests on the Operational Checklist?
YES
Recalibrate if device is out of calibration
(refer to pp 18)
Also recalibrate if any repairs or disassembly has been performed.
Service Action
(refer to pp 33)
NO
Record pump has passed service. Clean & return to customer
Troubleshoot
(refer to pp 28)

Customer and Device Information & Pre-Service Checklist

Before performing any service procedure:

1. **Authorized service personnel**
   Service of BodyGuard pumps may only be performed by authorized service personnel. Service can only be performed with the recommended equipment and CME approved parts.

2. **Confirm Customer Information**
   Confirm proper document record has been completed for, Log receipt, pump serial number & physical appearance (i.e. damage, signs of tampering).

3. **Disinfect the pump** according to cleaning instructions as described in the user manual.

4. **Open a service file to include all required documentation.**

5. **Download or View the Event Log -** The event log records program and calibration settings, and notes the frequency and nature of any alarms/alerts that may be associated with past pump performance or a complaint.

   Download the Event Log
   a. Use the BodyComm Software and Communication charger.
   b. Refer to the BodyComm Operations Manual:
      i. Connect BodyGuard to a PC using BodyComm.
      ii. Download and Record the Event Log
      iii. Download and Record Pump Settings.
      iv. Once done Power down the pump.

   Manual View the Event Log and History
   BodyGuard 323
   a. Start pump normal operation mode
   b. Enter Change Set up Mode by pressing INFO key until options are displayed.

c. Select Change Set Up, Press START/OK key
d. Scroll down to option “More”, Press START/OK
e. For BodyGuard 323 Enter Change Set Up Code
f. Scroll to option History, Press START/OK key.
g. Using arrow key scroll through events, Press INFO key for more detail.
h. Exit by pressing start/OK key

BodyGuard 545, & 575

a. Start pump normal operation mode
b. Enter Level 1 code, Press START/OK to enter Main Menu
c. Scroll down to Event Log, Press START/OK
d. Using arrow keys scroll through events, Press INFO key for more detail.
e. Exit by pressing START/OK key

Manual Review of Pump settings

a. Enter the Technician Menu (power up the pump while holding down the INFO & POWER keys simultaneously until the Technician Code prompt appears).
b. Enter Technician Code.
c. Scroll to ‘Manual Calibration’ and record all pump calibration settings (volume and pressure calibration) by pressing START/OK continuously to review each setting.
d. Scroll to and perform ‘Main Self-Test’ and record any failures or issues identified during the test.

6. Review Customer supplied Service Request Information

a. Has the user operated the pump correctly? Cross reference their report with the Operation’s Manual to ensure the steps they took prior to the incident did not cause, or result in, an alarm state or error code.

7. When the Pre-Service checklist has been completed, begin Service by performing the Operational Checklist.

a. If a charger was returned as a complaint item, test the charger with the associated pump cited in the complaint. If no pump was returned with the charger, process the charger as usual.

Tools and Test Equipment

The following tools and test equipment are required to perform the procedures contained in this manual. Since all fasteners on this device are metric, ensure that all tools used are for metric fasteners.

Test Equipment

- Digital voltmeter (Fluke 115 or equivalent)
- BodyGuard Operations Manual
- PC with a RS232 9way Serial port
- BodyComm Communication Software*
- BodyComm Operations Manual*
- BodyComm Communications Charger (150-318X)*
- BodyGuard Charger may be required (pulse oximeter charger for 545, and 575)
- RS 232 cable (197-000X)**
- ESD work station Mat and Wrist Strap
- BodyGuard tubing set with proximal Y-Site**
- Infusion Bag (sterile water for injection)
- Scale (.01g resolution)
- Pressure Gauge, maximum pressure 30psi, .01 psi resolution
- Timer (seconds resolution)
- Burning Station PN 100-405X* (for software updates)
- 5 pin male to male connection wire*
- Prog08sz software*

Tools

- Phillips screwdriver, M3
- Flat screwdriver, M3
- Allen key 2.5 mm
- Forceps
- 2mm Push shaft
- Air Sensor ‘Go No-Go’ gauge/or gauge pins (GO, 2.2 mm, No-GO, 2.3 mm)
- Sharp knife
- 3 ml Syringe with graduated markings
- DC Cable BG (196-000X)*

*Available only from CME
** Optional Equipment
Note: CME prefers the download of the pump settings, event log and/or history review be performed with BodyComm Software available from CME. However, when the software is not available the review and/or download can be performed manually.

Adjustable Operating Parameters and Options

BodyGuard 323

The BodyGuard 323 pump has adjustable operating parameters. These operating parameters and options may be viewed and adjusted to modify the operation of the pump. The operating parameters and options available for the BodyGuard 323 are described below in the Techncian Menu, Change Set Up Menu, Program Lock, and Keypad Lock sections. If access to a specific mode of operation is required (i.e. Continuous, Intermitent, PCA, TPN, or 25 steps), refer to the operation manual for instructions.

Technician Menu

To access the Technician Menu, press and hold the INFO key during the power on operation until 'Technician Code' prompt appears. The display will show the software version for 2 seconds before the access code prompt. Enter Technician Code to access the Technical Menu.

The pump will display all the parameters that can be set, calibrated or tested. The technician can scroll through all parameters using the ARROW keys (2 & 0 keys on the pump).

Item	Parameter	Description
1	Restart Pump	Exit Technician Mode.
2	Serial Number	Displays serial number & production date.
3	Manual Calibration	Summary of volume & pressure calibrations and ability to check/re-enter software default calibrations after service.
4	Main Self-Test	Performs keypad, display, alarm sound, door sensor, air sensor, temperature, motor & encoder, and pressure sensor tests.
5	Manual Test	Same as Main Self-Test but with a menu so technician can focus on individual tests.
6	Pressure Calibration	Allows manual calibration of pressure settings.
7	Volume Calibration	Allows manual calibration of pumping mechanism.
8	Software default Setting	**Caution**: pressing START/OK will restore software defaults and delete all pre-set protocols and set-up changes.
9	Reset Calibrations	**Caution:** pressing START/OK restores default settings. Pump must be re-calibrated after reseting calibrations.
10	Operating time/ hours counter	Hours from last service – reset to zero by pressing STOP/NO key.

Change Set Up Menu

To access Change Set Up Menu:

1. Turn the pump on in the normal operation mode.
2. To access the Change Set Up Menu, press the INFO key multiple times until the "Change Set Up" option is displayed,(it is always displayed as the 4th option).
3. Select "Change Set Up", press OK.
4. Scroll down to the option "More", press OK.
5. Enter access "Change Set Up" Code, press OK.

The Change Set Up Menu is intended for use by clinical personnel and authorized service technicians.

Item	Parameter	Description
1	restart pump	Allows clinical personnel to return pump to normal operation mode.
2	pressure default	Allows clinical personnel to set the default occlusion alarm pressure. The pump will default to this pressure setting each time the pump is started.
3	select program	Allows clinical personnel to select program from list (Continuous, Intermitent, PCA, TPN, or 25 steps).
4	priming rate	Allows clinical personnel to set priming rate.
5	max bolus volume	Allows clinical personnel to set maximum bolus volume (0-100 ml).
6	titration bolus	Allows clinical personnel to set titration bolus (On/ Off).
7	bolus rate	Allows clinical personnel to set bolus rate (0-1200 ml/h).
8	maximal rate	Allows clinical personnel to set maximal rate (0.1-1200 ml/h).
9	KVO rate	Allows clinical personnel to set KVO rate (0.0-5.0 ml/h).
10	flow control	Allows clinical personnel to set flow control (0 - 20 drops/ml).
11	set loading test	Allows clinical personnel to activate set loading test (On/Off).
12	air bubble size	Allows clinical personnel to set air bubble size (0.1 - 2.0 ml).
13	store last program	Allows clinical personnel to store last program (On/Off).
14	operation LED	Allows clinical personnel to set operational indicator LED (On/Off)
15	time option	Allows clinical personnel to set time option (On/Off).
16	delay before start	Allows clinical personnel to set delay before start (On/Off).
17	language	Allows clinical personnel to choose language (English, Spanish).
18	set time and date	Allows clinical personnel to date and time (dd, mm, yy, hh, mm).
19	history	Allows clinical personnel to review event history settings and alarms (for last 500 events)

Program Lock

To access Program Lock:

1. Turn the pump on in the normal operation mode.
2. To access the Change Set Up Menu, press the INFO key multiple times until the "Change Set Up" option is displayed,(it is always displayed as the 4th option).
3. Select "Change Set Up", press OK.
4. Scroll down to the option "More", press OK.
5. Enter Program Lock Code, press OK.
6. Select ON to activate lock (Off/On).

The Program Lock is intended for use by clinical personnel and authorized service techncians.

Item	Parameter	Description
1	Locks ability to change programs	Enables clinical personnel to lock out the pump so that programs can only be started or stopped.

Keypad Lock

To access Keypad Lock:

1. With the pump operating in normal operation mode, to activate the Keypad Lock: Press and Hold the INFO Key until the bar graph is filled.
2. Repeat step 1 to deactivate.

The Keypad Lock is intended for use by clinical personnel and authorized service technicians.

Item	Parameter	Description
1	Locks all keypad buttons except the INFO START/OK and STOP keys	Enables clinical personnel to lock all buttons but the INFO, START/OK and STOP keys to prevent tampering with the pump during normal operation.

BodyGuard 545 and BodyGuard 575

The BodyGuard 545 and 575 pumps have adjustable operating parameters. These operating parameters and options may be viewed and adjusted to modify the operation of the pump. The operating parameters and options available for the BodyGuard 545, and 575 are described in the Technician Menu, Level 1 Menu and Keypad Lock.

Technician Menu

To access the Technician Menu, press and hold the INFO key during the power on operation until 'Technician Code' prompt appears. The display will show the software version for 2 seconds before the access code prompt. Enter Technician Code to access the menu.

The pump will display all the parameters that can be set, calibrated or tested. The technician can scroll through all parameters using the ARROW keys (2 & 0 keys on the pump).

Item	Parameter	Description
1	Restart Pump	Exit Technician Mode.
2	Serial Number	Displays serial number & production date.
3	Manual Calibration	Summary of volume & pressure calibrations and ability to check/re-enter software default calibrations after service.
4	Main Self-Test	Performs keypad, display, alarm sound, door sensor, air sensor, temperature, motor & encoder, and pressure sensor tests.
5	Volume Test	Program rate & volume to be delivered during flow rate test.
6	Manual Test	Same as Main Self-Test but with a menu so technician can focus on individual tests.
7	Pressure Calibration	Allows manual calibration of pressure settings.
8	Volume Calibration	Allows manual calibration of pumping mechanism.
9	Software default Setting	**Caution**: pressing START/OK will restore software default defaults and delete all pre-set protocols and set-up changes.
10	Reset Calibrations	**Caution:** pressing START/OK restores default settings. Pump must be re-calibrated after reseting calibrations.
11	Operating hours	Hours from last service – reset to zero by pressing STOP/NO key.
12	Access Codes	Displays current access codes and allows change.

Level 1 Menu

To access Level 1 Menu:

1. Turn pump on.
2. Prompt reads “Press OK to Resume or Press NO for Menu”.
3. Press No to access menu
4. Enter Level 1 Code, Press OK

The Level 1 Menu is intended for use by clinical personnel and authorized service technicians.
Access to specific parameters requires entering Admin or Clinician Activate Bolus access codes.

Item	Parameter	Description
1	Prime	Allows clinical personnel to prime set.
2	Select Protocol	Allows clinical personnel to select protocol (New patient, Previously programmed).
3	Change Bag	Allows clinical personnel to change bag. 1. Start New Bag 2. Confirm bag volume (Ok/No) 3. Start Infusion (Ok/No)
4	Modify Protocol	Allows clinical personnel to modify protocol by entering Admin Code.
5	Clinician Bolus	Allows clinical personnel to deliver a bolus regardless of preset limits by entering Clinician Activated Bolus Code.
6	Patient History	Allow clinical personnel to display infusion history for last 24 hours.
7	Event Log	Allow clinical personnel to review event history settings and alarms for last 500 events)
8	Battery Test	Allow clinical personnel to perform battery capacity test.
9	Review Set Up	Allows clinical personnel to review: 1. Pulse Oximeter 2. Battery Level 3. Program Lock 4. Time and Date 5. Tube temperature 6. Key Stroke Volume 7. Occlusion Pressure 8. Priming Volume 9. Priming Rate 10. Max CA Bolus 11. Default Bolus Rate 12. Maximum Basal Rate 13. KVO Rate 14. Program Limits 15. Air In Line Limits

		16. LED Indicator 17. Bolus Key 18. Titration Option 19. Serial Number 20. Production date 21. Operating Hours 22. Software Version 23. Volume Calibration 24. Pressure Delta 25. Pressure Cap 26. Exit
10	Change Set Up	Allow clinical personnel to Change Set Up by entering Admin Code. 1. Pulse Oximeter a. Enable/Disabled (Requires a pulse oximeter charger) b. Program alarm limits i. Pulse Limit (< Limit,> Limit) ii. SPO_2 saturation (< Limit) c. Sync Pulse Audible i. Enable/Disable 2. Key Stroke Volume (bar graph) 3. Occlusion Pressure [545 (7/14/21psi)], [575 (5/7.5/10 psi)] 4. Priming Volume (0-20 ml) 5. Priming Rate (300-1200 ml/h) 6. Max CA Bolus (disable/limit max clinician bolus dose to 0-20 ml) 7. Default Bolus Rate (0-1000 ml/h) 8. Maximum Basal Rate (0.0-30 ml/h) 9. KVO Rate (0.0 - 5.0 m/h) 10. Program Limits - Set MediGuard limits for body weight (On/Off) 11. Air In Line Limits - (0.0 - 1.0 ml) 12. LED Indicator - Set operational indicator LED (On/Off) 13. Bolus Key - Allows clinical personnel to enable/disable the keypad bolus key. 14. Titration Option - Allows clinical personnel to set titration Option (On/ Off). 15. Set Time and Date - Allows clinical personnel to date and time (dd, mm, yy, hh, mm). 16. Restart Pump - Allows clinical personnel to return pump to normal operation.

Keypad Lock

To access Keypad Lock:

1. With the pump operating in normal operation mode, to activate the Keypad Lock: Press and Hold the INFO Key until the bar graph is filled.
2. Repeat step 1 to deactivate.

The Keypad Lock is intended for use by clinical personnel and authorized service technicians.

Item	Parameter	Description
1	Locks all keypad buttons except the INFO START/OK and STOP keys	Enables clinical personnel to lock all buttons but the INFO, START/OK and STOP keys to prevent tampering with the pump during normal operation.

Operational Checklist and Performance Acceptance Test

Introduction

The Operational Checklist and Performance Acceptance Test detailed in this section determines if the device is operating correctly. The Operational Checklist and Performance Acceptance Test should be carried out before any service work is performed. If the device fails any test in the checklist, the fault must be recorded and corrected prior to placing the device back into clinical use. Any test failures should be analyzed using the troubleshooting procedure that follows to determine service action. After all service is completed, the Operational Checklist and Performance Acceptance Test should be repeated and the device should be re-calibrated if required.

If the returned device is a complaint, the device should be tested with any associated products (i.e. sets, etc). Devices subject to complaint evaluation should be tested to try to duplicate the customer's complaint. Once the complaint evaluation with the associated product has been completed the device should be retested without the associate product to the normal service process.

1. **Main Self Test**
    a. Keypad test - Tests operation of all keypad keys.
        i. Test passes if all keys work
    b. Display Test - Tests all pixels back light.
        i. Test passes if all pixels work
    c. Acoustic alarm test - Tests volume of alarm.
        i. Test passes if alarm volume can be heard from 20 feet.
    d. Door position test - Tests door open alert.
        i. Test passes if screen displays "Closed" when door is closed, and "Open", when door is open.
    e. Air sensor test - Qualitative test of air sensor functionality.
        i. Test passes if alert activates when air is present in front of air sensor.
    f. Motor Test - Qualitative test of motor functionality.
        i. Test passes if display reads "pass".
    g. Pressure Sensor Test - Qualitative test of pressure sensor functionality.
        i. Test passes if screen displays 50+/- 2.

2. **Open Door Alert Function**
   a. Perform door open test – Open door during infusion and verify alarm.
   b. Open door alert test is passed if alert activates when door is opened.

3. **Air Detect Function**
   a. Load a primed BodyGuard tubing set into pump.
   b. Attach a y-site upstream of the pump.
   c. Using a 3 ml syringe, inject 1.1 ml of air into the line - alarm should activate once the air bubble passes the sensor. This test will demonstrate the accumulation of air bubbles of 1 ml over 15 minutes (user should check Air Limit is set to 1ml under 'Change Set Up').
   d. Test is passed if air alarm activates under 1 ml.

4. **Battery Operation Test**
   a. Discharge battery to "End Battery".
   b. Charge battery until green charge indicator light turns on.
   c. Program pump to 1200ml/hr.
   d. Start pump and start timer and run to "End Battery".
   e. Record time to discharge pump.
   f. If battery ran for at least 3 hours, battery passes, if battery did not, replace battery.

5. **Restore Software Default Settings (page 46)**
   a. Check software default settings are restored. (User programmable protocols should be blank)
   b. Test is passed if they are set to Software default values.

   Note: Complaint pumps will have software default settings restored after notification of complaint closure.
   c. Check that Software Default Settings were restored
   d. Software default settings should only be restored before beginning the last Operational Checklist and Performance Acceptance Test after service has been completed.

6. **Pole Mount Charger Voltage Test (page 35)**
   a. Using voltmeter, measure pin voltages diagrammed in section 1.3 Replacing Charger PCB

7. **Verify DC Extension Cable Connector Operation**
   Turn pump on and start an infusion. Plug DC extension cable to charger and pump. Verify that battery charge icon on charger is lit. Verify that the battery icon on the pump turns off.

8. **Volume Delivery (page 22)**
   a. Perform Volume Delivery Calibration procedure to obtain assessment.
   b. Volume delivery test passes if volume delivered is setting +/- 5%.

9. **Occlusion Pressure (page 26)**
   a. Perform Occlusion Pressure Calibration procedure to obtain assessment.
   b. Occlusion pressure test passes if pressure limit +/- 2 psi is achieved.

10. **Ground Strap Test**
    a. Test continuity between center charger connector pin and door hook. If no continuity, ship to CME America for installation.

11. **QC and Calibration Labels**
    a. Upon completion of the Service and the Operational Checklist and Performance Acceptance Test, place a QC label on the pump indicating "QC Approved" as a tamper proof indicator and place a calibration label on the pump indicating the "date of calibration" and "initials of the technician" performing the calibration.

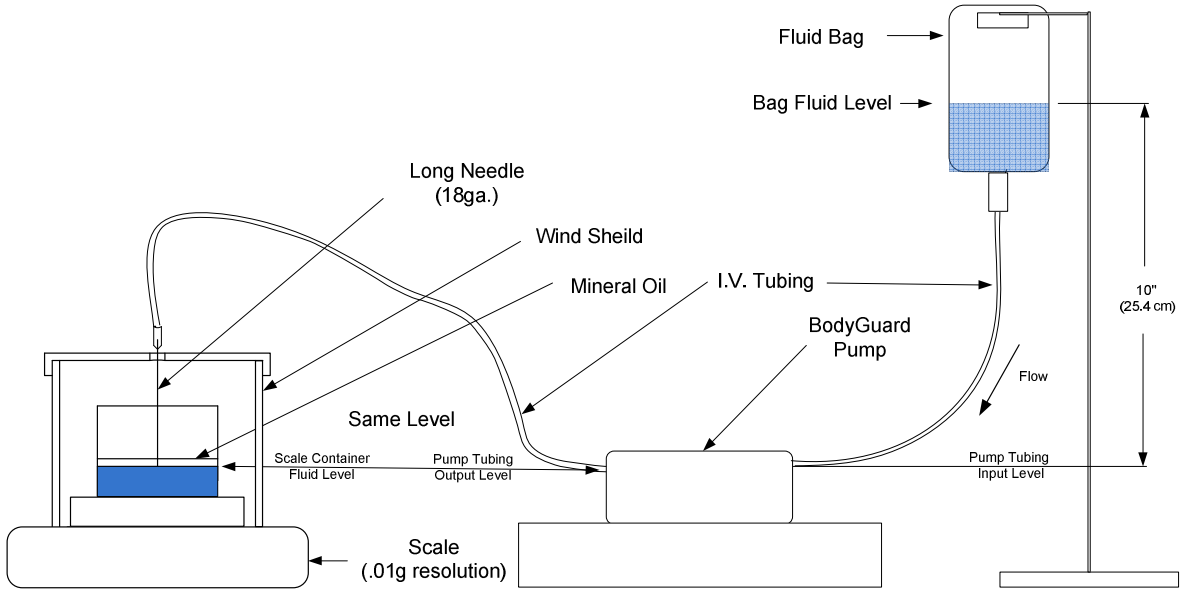
Calibration

Volume Calibration

Background:

Volume calibration is performed to enable the pump to deliver accurately.

Perform the volume calibration using the test set-up diagramed below.



BodyGuard 323, 545, & 575
Delivery Accuracy Measurement & Calibration Test Set-Up Diagram

Acceptance Criteria:

The pump must be within +/- 5% to pass this test.

Required Equipment:

Scale with 0.01 gm degree accuracy
BodyGuard tube set
Collection vessel
IV bag
BodyGuard pole mount charger and power cord
IV pole or similar mounting surface
BodyGuard Pump

Procedure:

1. Fill the IV bag with room temperature sterile water. It is important that the water be room temperature so that it does not affect the elastic properties of the silicone replacement pumping segment. Once the IV bag has been filled, use a BodyGuard tube set to spike the IV bag. Hang the IV bag and the tube set from the IV pole. To prevent fluid coming into contact with the air sensor and pumping mechanism, the infusion bag should be spiked before opening the pump door. Position the bag so that the risk of spillage onto/into the device is minimized. **Do not stretch the set when removing it from its packaging or installing it in the pump.**

2. Attach the BodyGuard pole mount charger so that the pumping chamber is 10" below the IV bag on the IV pole. This will ensure that the pumping segment will reach the pumping chamber once the pump has been inserted into the pole mount charger. Load the pump into the pole mount charger and insert the pumping segment of the tube set into the pumping chamber.

3. Power on the pump and set the BodyGuard 323 parameters in the following table using steps below:

Scroll through the menu and adjust the values so that they match the table below. Setting	Required Value
Pressure Default	14 PSI
Pump Program	Continuous
Maximal Rate	1200 ml/hr
KVO Rate	0.0 ml/hr
Set Loading Test	Off
Time Option	Off

   a. Press the INFO button until the option "Change Setup" appears. Press the Start/OK button.
   b. Using the down arrow (zero button scroll to the option) "More" and press the Start/OK button.
   c. Enter Change Set Up Code and press the Start/OK button.
   d. Scroll through the menu and adjust the values so that they match the table above.
   e. Once all values have been confirmed, select the option "Restart Pump".

4. To calibrate volume for the BodyGuard 545 and 575, use the "Volume Test" found in the technician menu and disregard step 3.

5. Prime the tube set by pressing the Prime/Piggy button (for 323) or Bolus button (for the 545/575) and set a volume that will completely prime the tube set. The priming volume of the set will be listed on the tubing package (in most cases 20 ml will be more than enough volume to expel all air from the set). After priming place the open end of the tube set into the collection vessel and begin the priming function. Once priming is complete, weigh the collection vessel and record the result.

6. Insert the open end of the tube set into the collection vessel and start an infusion at a rate of 125 ml/hr at a volume of 20 ml.

7. Once the infusion has finished, weigh the collection vessel and record the result. Subtract the pre delivery weight (the amount from the priming operation in Step 5) from the post delivery weight. This number is the actual volume delivered. The expected delivery is the volume programmed on the pump to be delivered. Use the following equations to calculate the infusion rate error:

$$Post\ delivery\ weight - Pre\ delivery\ weight = Actual\ delivery$$

$$\frac{Actual\ delivery - Expected\ delivery}{Expected\ delivery} * 100 = \%\ difference\ error$$

8. If the results from step 7 is not within the +/- 5% range the pump must be recalibrated. Begin this process by entering the Technician Menu using the appropriate Technician Code.

9. Scroll to the option titled “Manual Calibrations” and press the start OK key.

10. Use the following equation to determine the amount of adjustment needed to recalibrate the volume delivery.

$$\%\ Difference\ Error\ x\ 5 = Correction\ Value$$

11. Adjust the four volume settings in the Manual Calibration menu by the Correction Value obtained in step 10.

Note: If the Correction Value from step 10 is a positive number subtract this number from the current calibration number. If the Correction Value from step 10 is a negative number add this number to current calibration number.

Example: *(positive correction value)*

Percent difference error = 4
Correction value = 5x4=20
Current calibration value = 535
Corrected calibration value = 535-20 = 515

Example: *(negative correction value)*

Percent difference error = -3
Correction value = 5x-3 = -15
Current calibration values = 535
Corrected calibration value = 535- (-15) = 550

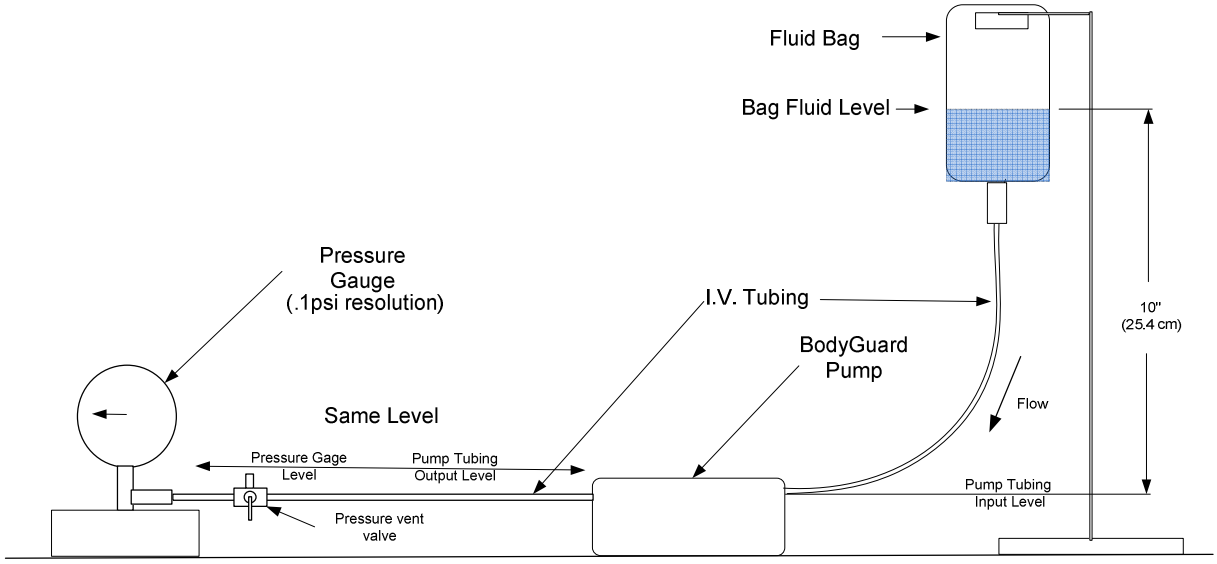
12. Repeat step 5 through step 10 until the pump is within the +/- 5% specification criteria. A result from the test in Step 5 that is within +/- 5% for the pump meets the acceptance criteria.

Note: Should you have any questions about the procedures described herein or any other BodyGuard product questions, please contact the CME America Service Center.

Occlusion Pressure Calibration

Background:

Occlusion pressure calibration will allow the pressure alerts to activate correctly. The calibration is accomplished by adjusting the pump to display the correct pressure at two different pressure levels. This will enable the pump to display the pressure accurately anywhere within the operational range to the specification tolerance. Perform the Occlusion Pressure Calibration using the test set-up diagramed below.



BodyGuard 323, 545, & 575
Pressure Calibration Test Set-Up Diagram

Acceptance Criteria:

Alarm should occur at 10+4/-2psi for BodyGuard 575 and 14+4/- 2 for the BodyGuard 323, & 545.

Required Equipment:

Pressure Gauge (.1 psi resolution)
BodyGuard tube set
Collection vessel
IV bag
BodyGuard pole mount charger and power cord
IV pole or similar mounting surface
BodyGuard Pump

Procedure:

1. Press and hold the INFO key, while switching the pump on. Wait until the screen displays 'Technician Code.' Enter the appropriate Technician Code, and press START/OK key to enter.
2. Use the ARROW keys to scroll to Pressure Calibration option. Once this option is displayed (in double size letters) press START/OK key to enter.
3. Pressure Cal shows on display:

Pressure Sensor Test 50 (2.1v) Press OK to continue

   Pump door should be open without a BodyGuard tubing set installed. The value on the screen will set 50±2. Press START/OK key to store this setting. This value represents the zero level of the pressure sensor when the BodyGuard tubing set is not in place. The voltage value in brackets should be less than 5V. If this voltage is over 5V, the pressure sensor may be faulty. Replace sensor and recalibrate.
4. The (2.1V) is showing the status of the pressure Potentiometer.
5. Load an unprimed BodyGuard tubing set into the pump. Insert the key in the key recess and close the pump door. The reading of the pressure sensor will change; wait about 10 seconds until this reading stabilizes.

Pressure Calibration 85 Set 0 PSI, Press OK

6. Press the START/OK key. This sets the zero level of the pressure sensor with a set loaded.
   Note: The zero level data will remain in the pump memory until changed.

BodyGuard 323, & 545

Pressure Calibration 85 Set 14 PSI, Press OK

BodyGuard 575

Pressure Calibration 85 Set 10 PSI, Press OK

7. Prime the BodyGuard tubing set and connect a pressure gauge to the end of the administration set. The pump will display the pressure required.
8. Press the ARROW UP key to increase the pressure to the required level.
9. If in adjusting the pressure setting, the desired value is exceeded, relieve the pressure in tube and start again at step 11.
10. Once the pressure gauge shows the correct pressure level, press the START/OK key.
11. Increase pressure to 30 PSI and confirm with START/OK key.

Pressure Calibration 119 Set 30 PSI, Press OK

12. The pump will use these values to automatically calculate the values required for pressure calibration.
13. Release the built-up pressure by disconnecting the set from the pressure gauge and reconnecting it.
14. Enter Manual Calibration (in Technician Mode) change pressure cap option to 255 using the keypad.
15. Test pressure alarm under normal operation. Connect a pressure meter at the end of the tubing. Alarm should occur at 10psi +4/-2psi for BodyGuard 575 and 14+4/- 2 for the BodyGuard 323, & 545.
16. Repeat calibration procedure if result of 1st calibration does not meet acceptance criteria.

Troubleshooting

Use the troubleshooting guide below to identify probable service action.
Once a service action plan has been developed refer to service action section for service action procedure.

Alarm or Problem	**Possible cause**	**Action**
Pump does not switch on	Battery depleted	Click the pump into a charger connected to AC power
	Battery malfunction	Replace Battery
	On/off key malfunction	Replace the main PCB (ref. sec. 5.1)
Missing Key	Unauthorized set used	Replace non-CME set. Use only BodyGuard tubing set
	Pressure calibration incorrect	Repeat pressure calibration
Error 1, Motor turns without control or motor can't turn	Mechanical malfunction	Check for mechanical obstruction of the cam shaft and gears.
	Electronic malfunction	Replace Motor PCB (ref. sec. 5.1)
Error 7	Wrong pressure calibration	Repeat pressure calibration procedure if persists, replace pressure sensor
	Pressure sensor malfunction	Replace pressure sensor and recalibrate. (ref. sec. 3)
Error 10	Mechanical malfunction	Turn the pump off and on again and set pump to operate on 0.1 ml/hr
Error 11	Mechanical malfunction	When the motor can't turn, check for mechanical obstruction. If the problem persists, replace motor PCB.
Error 12	Mechanical malfunction	Turn the pump off and on. If the problem persists, replace motor PCB.
Error 13	Encoder malfunction	Visually check encoders and verify no mechanical obstruction
	Microprocessor malfunction	Replace main PCB (ref. sec. 5.1)
Error 15	Microprocessor malfunction	Replace main PCB (ref. sec. 5.1)
Error 16	Electronic malfunction	Replace main PCB (ref. sec. 5.1)

Error 17	Electronic malfunction	Replace main PCB (ref. sec. 5.1)
Error 19	Electronic malfunction	Turn the pump off and on. If the problem persists, replace main PCB.
Error 20	Microprocessor malfunction	Replace main PCB (ref. sec. 5.1)
Error 21	Microprocessor malfunction	Replace main PCB (ref. sec. 5.1)
Error 23	External Timer Battery depleted	Turn the pump off and on again - if problem continues replace Li-ion 3V battery
Error 24	External interrupt or electronic malfunction	Turn the pump off and on again - if problem continues replace main PCB (ref. sec. 5.1)
Error 25	Battery malfunction	Ensure pump can be operated on battery power
	Pump contacts are not clean	Make sure pump contacts are clean
	Short in DC connector	Remove mechanical obstruction from DC connector
	Electronic malfunction	Replace main PCB (ref. sec. 5.1)
Error 26 Mechanical obstruction, motor connector not reconnected, or gear box separation.	Motor Test Failed	Check for mechanical obstruction, verify the motor is connected, and verify the gear box has not separated from the motor.
		Motor PCB malfunction (ref. sec. 5.1)
Error 27	Electronic malfunction	Replace main PCB (ref. sec. 5.1)
Error 28	Encoder detects external light	Make sure pump case is closed with 4 screws (ref. sec. 2.1)
	Encoder malfunction	If pump is properly closed, replace motor PCB (ref. sec. 5.1)
Error 30	Memory malfunction	Turn the pump off and on again - if problem continues: 1. Restore Software Default Settings (ref. Sec. 8 steps 1-8) 2. Recalibrate pump If problem continues: 3. Replace main PCB (ref. sec. 5.1)
Error 32	External interrupt	Turn the pump off and on again - if problem continues replace main PCB (ref. sec. 5.1)
Error 33	Microprocessor	Replace main PCB (ref. sec. 5.1)

	malfunction	
Error 34	Microprocessor malfunction	Replace main PCB (ref. sec. 5.1)
Error 35	Wrong Pressure calibration	Repeat occlusion pressure calibration procedure. If persists, replace pressure sensor.
	Pressure sensor malfunction	Replace pressure sensor per instructions. (ref. sec. 3)
Error 39	Microprocessor malfunction or software code corrupted	Burn software again - if an error occurs during or after burning the software, replace main PCB (ref. sec. 5.1)
Air in Line alarms	Dirty air sensor surface	Clean air sensor surface
	Scratches on the air sensor surface	Replace air sensor per instructions. (ref. secs. 4.1 and 4.2)
	Air sensor malfunction	Perform air sensor test at Technician Menu, under Manual Test - air sensor
	Main PCB malfunction (Door or front sensor)	Perform air sensor test If persists, replace door air sensor. If persists, replace main PCB.
Door open alarm	The door magnet has fallen out	Install a door magnet (ref. sec. 2.3)
	The door does not close properly	Clear or adjust the door mechanism (ref. sec. 2.4)
	The reed switch has malfunctioned	Replace the Main PCB. (ref. sec. 5.1)
Operation LED is not working	The operation LED is turned off (Change Set-Up)	Enter Change Set-Up and switch LED to "On"
	Operation LED malfunction	Change the main PCB (ref. sec. 5.1)
Battery life limited	Battery weak/damaged	Perform battery test described in Operational Checklist and Performance Acceptance
Unable to set higher flow rate	The maximal rate has been capped in 'Change Set up'	Change the maximal rate to higher limit in 'Change Set Up'
The charging LED does not illuminate when the charger is	AC plug is not securely inserted into the charger socket or mains.	Press power plug firmly into the charger socket and AC plug.

connected to AC power	The power cord is in poor condition Check output pins of AC/DC Should be 10v± 0.5v	Replace power cord if necessary If 0v, check fuses or replace charger PCB (ref. secs. 1.1 and 1.2)
The battery LED indicator does not illuminate while the pump is in the charger and connected to AC power	Poor battery output Connectors between charger and pump are dirty Motor PCB malfunction	Replace battery if required Clean connectors Replace motor PCB (ref. sec. 5.1)
The green battery LED does not illuminate while the pump is connected to charger (AC connected) within 2 to 4 hours after charging from Low Battery"	Check output of battery (5 – 8.4v)	Replace battery if required. If persists, replace charger PCB
Date of Manufacturer is 0, S/N is 0	Real Time Clock Battery power has been disconnected	When the Real Time Clock battery has been disconnected or replaced, all program settings will reset. Reenter Manufacturer Date and S/N through S/N option in Technician Menu.
Pulse Oximeter is not working properly	Pulse oximeter is not connected Pulse oximeter function is not enabled Pulse oximeter is not working	Service per (Ref. sec. 1.4) (Ref. sec. 1.4)

	Pulse oximeter charger not working	
Down level software version on pump	Release of new software version	Upgrade software version of pump. (ref. sec. 7)
Request for specific software version	Customer request	Program pump with requested software version (ref. sec. 7)
Programmable protocols are still programmed	Software default setting have not been restored	Restore software default settings (ref. sec. 8)
If after exhausting all diagnostic and service options the pump still does not operate correctly.	Unknown	Return pump to customer with recommendation to remove from use.

Service actions

Introduction

Once the cause of failure has been identified, use the appropriate service action below to correct the problem.
To ensure the device is operational, ALWAYS repeat the Operational Checklist after completing any of the procedures in this section.

General Disassembly / Assembly of Pump and Charger

Disassembly of the pumps and charger is limited to complete subassemblies and mechanical components. It is recommended that electrical problems be corrected by replacing the entire PCB. Use only the replacement parts supplied by the manufacturer or an authorized distributor. Read ALL steps in a procedure before undertaking the work. The procedures are given in order of disassembly and then reassembly. Disassemble the device only as far as required to complete a service. All fastening components such as screws, washers and nuts used in the device are metric - be sure to use metric tools and replace only with metric components. Refer to Appendix A for pictures of disassembled pumps and chargers.

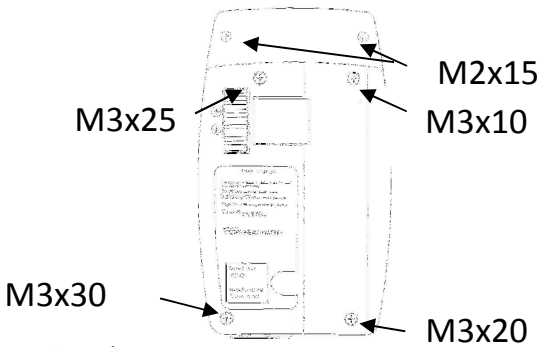
Caution: The components inside the device are sensitive to electrostatic discharge (ESD). Always wear a grounded wrist strap and use a protective ESD mat when performing service on the device to prevent damage to components.

1. Disassembly / Assembly of Pole Mount Charger

Warning: When servicing the charging device, ensure the device is unplugged before disassembling. Failure to do so can result in personal injury, death and /or damage to the device.

1.1 Disassembly of the Charger:

1. Remove pump from charger.
2. Disconnect charger from AC power.
3. Remove the 6 screws as shown in the diagram and separate the case.
4. The PCB is now loose and can be removed from the front housing.



Caution: When separating

5. To reassemble the charger, ensure all connecting wires are secure.
6. Insert the correct length of screw into the hole shown and tighten.

case, be careful of connecting wires.

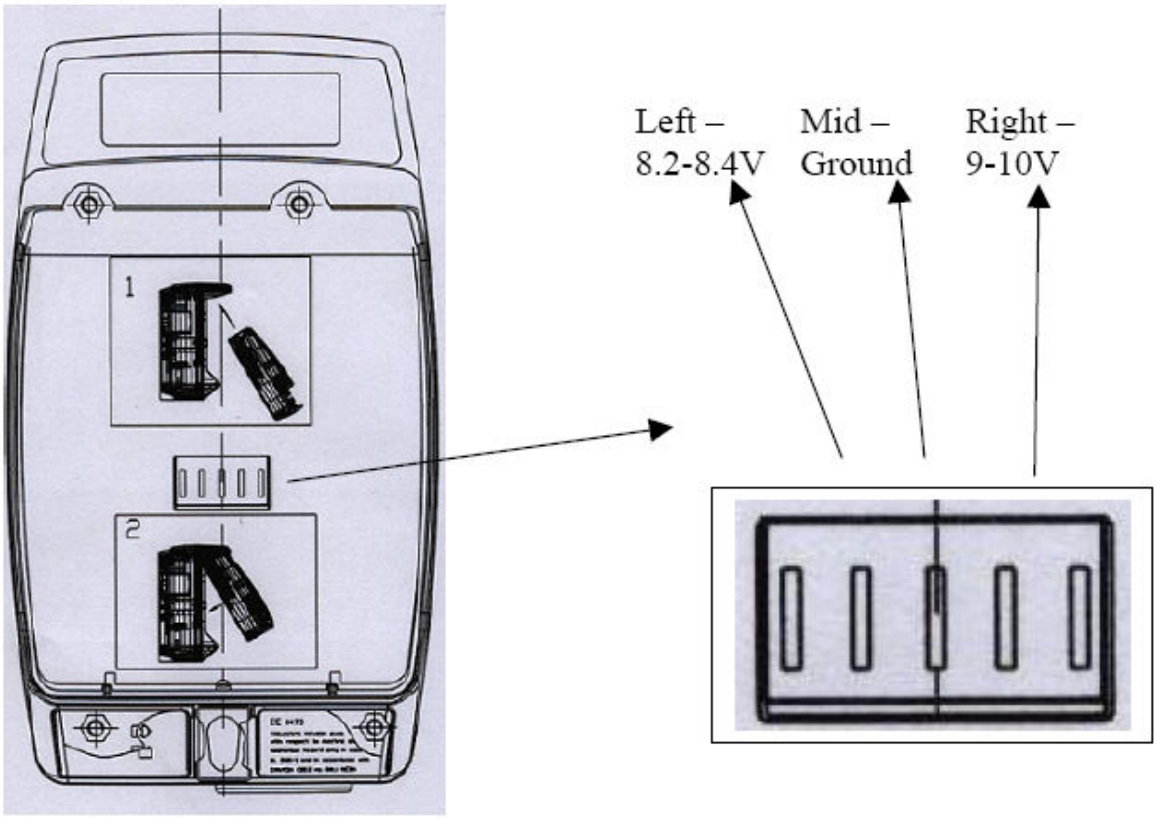
1.2 Replacement of AC Power Fuses in Charger Unit

1. Remove the pump from charger.
2. Connect the charger to AC power.
3. Check that the AC power icon is displayed, if not perform the following steps:
    a. Remove the AC cable from the power outlet.
    b. Disassemble the charger following the "Disassembly / Assembly of Charger" instructions above.
    c. The fuses are protected by a plastic cover on the back of the AC power inlet, remove this cover.
    d. Remove the fuses from the fuse holder on the charger PCB, and using an ohmmeter check electrical continuity.
    e. If necessary, replace with a new fuse of same value, type and voltage. F1, F2 20mm 800mA Slow Blow.
    f. Replace plastic fuse protection cover.
    g. Reassemble charger in reverse order.
4. Perform Operational Checklist and Performance Acceptance Test

1.3 Checking Charger Voltage

WARNING: Voltage present on internal components may cause severe shock or death upon contact. The following procedure requires measuring voltages with the case open. Use care when making these measurements.

1. Check the input voltage on the AC/DC converter (should be between 100-240 V). If not, check fuses. If so, check the output pins of the AC/DC converter should be 10V±0.5v. If 0v, replace the PCB.
2. Verify the voltages diagrammed below.
3. Perform Operational Checklist and Performance Acceptance Test



1.4 Pulse Oximeter Charger

1. Plug in Pole Mount Charger with Pulse Oximeter connector.
2. Attach working pump to charger.
3. Enable Pulse Oximeter feature through Change Set Up Menu
4. Note on service record, if Pulse Oximeter feature was not enabled.
5. If it was enabled, attach working Pulse Oximeter to connector.
6. Activate Pulse Oximeter by starting program.
7. If it does not work replace Charger.
8. Perform Operational Checklist and Performance Acceptance Test

2. Disassembly / Assembly of Pump

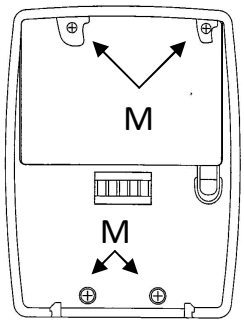
2.1 Separation of front and rear housing

Note: Always disassemble the pump on and ESD work surface with wrist strap secured. Failure to do so could cause damage to the internal components of the pump.

1. Turn the pump off and place it face down on an anti-static mat or ESD-grounded work surface. Make sure there are no metal parts (including screws and nuts) on the working surface in order to avoid scratching the pump housing.

2. Remove the battery from the rear housing. First lift up the battery release handle and pull out the battery bottom first.

3. Remove the 4 mounting screws. These 4 screws connect the front and rear housing. 2xM2 screws are located under the battery compartment. 2xM3 screws are located on the lower portion of the housing. Remove the QC approval label to reveal these two screws.



4. Separate the front and rear housing by holding the front housing firmly against the ESD mat and lifting the rear housing vertically away from the front housing. Remove the screws from the rear housing and set them aside for later use.

2.2 Reassemble the housing

1. Place the front housing face down on the ESD mat and lower the rear housing onto it so that the seams of the two parts line up correctly. Do not use excessive force to reassemble the front and rear housing. If resistance is encountered, ensure that the connector between the front and rear housing is lined up properly.
2. Reinstall the 4 mounting screws.
3. After reassembling, switch the pump ON and perform the Self Test.
4. If service has been completed, perform Operational Checklist and Performance Acceptance Test

2.3 Replacement of Pump Door Magnet

1. Replace missing door magnet by securing new magnet into recess in top of door with press fit or glue.
2. Assure that magnet triggers door open alert and does not interfere with door operation.
3. If service has been completed, perform Operational Checklist and Performance Acceptance Test.

2.4 Replacement of Pump Door or Replacement of Pressing Plate

1. Use a 2.5 mm hex key to remove the security grub screws (M2 x 5) at both ends of the hinge (as shown on the diagram).
2. Using a Phillips head screw driver, remove the door-mounted air sensor, fixed with one M2 screw. Pull the sensor out from its recess.

3. Lift the air sensor cable and carefully using a 2 mm shaft, push the hinge pin from the air sensor side (left side) and remove it from the pressure sensor side. THE HINGE PIN WILL ONLY GO ONE WAY. The hinge pin must be removed from the right side of the pump and reinserted into the right side of the pump. Pushing the hinge pin the wrong way will cause damage to the pump.

4. Removing the hinge pin allows for separation and removal of the door, pressing plate, and springs.

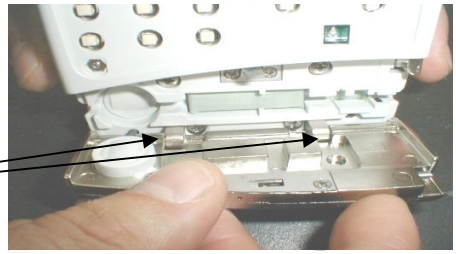
5. Replace the door, pressing plate and springs as needed.

   Note: Use caution when removing the door from the pump as the pressing plate springs are not attached to the door or the pressing plate.

6. Reassemble the door, pressing plate and springs as follows:

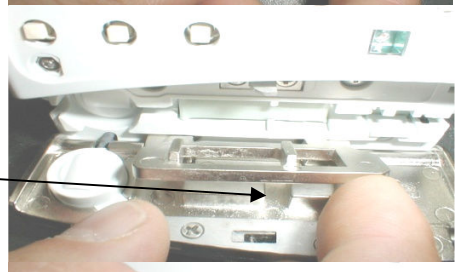
7. Place the door between the two visible parts of the hinge pin support features on the chassis block.

hinge pin support features



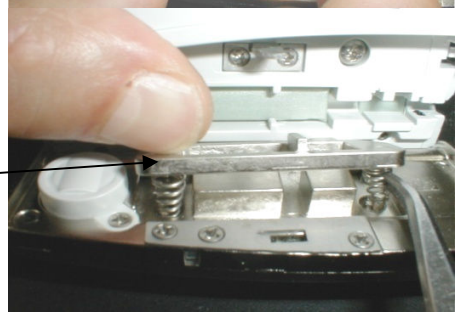
8. Place the pressing plate into the recess in the door.

door recess



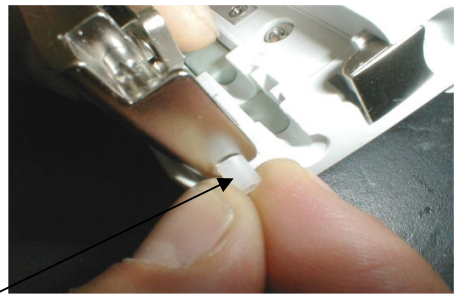
9. Lift the pressing plate and place the two door springs into their recesses in the door and pressing plate.

door springs

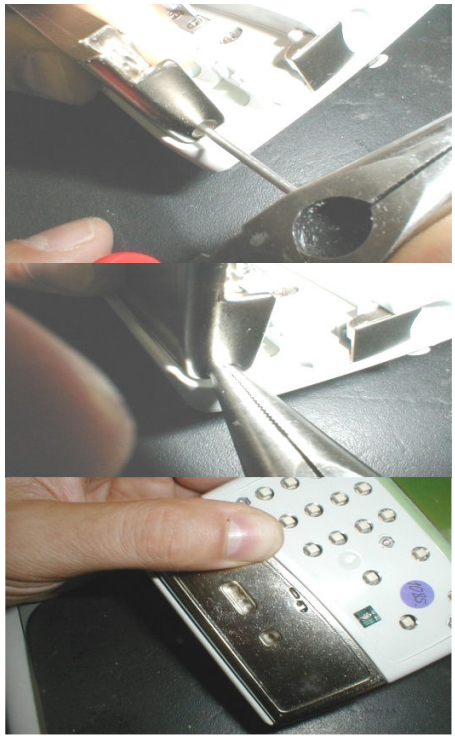


10. If you are fitting a new door or pressing plate ensure that Nylon bushings are present. Place bushings into the hinge holes of the new part. 6 bushings total are required for the door, pressing plate, and hinge support features.

Nylon bushing

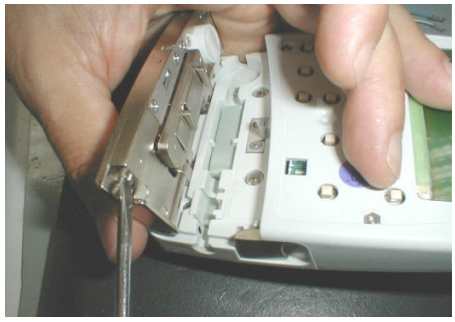


11. Push the hinge shaft from right to left through the door, pressing plate and the chassis block.



12. 12. Ensure the shaft has been inserted all the way into the hinge. Ensure the hinge pin does not interfere with the Door air sensor wiring.

13. To obtain correct door hook alignment, close the door. Make sure the door does not rub on the door hook. If it rubs, readjust the door hook by bending it slightly. Operate the door and readjust the door hook if necessary until a click is heard from the door catch.



14. Verify the door releases when door latch is ¾ open. Close the door. Pull the door latch out about ¾ open and verify that the door opens. If the door does not open at this point, use a flat tip screw driver to adjust the latch mechanism by turning the screw as shown in the picture. Repeat this adjustment until the door operates as specified.

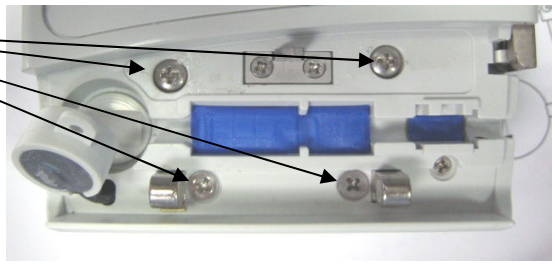
15. Perform Operational Checklist and Performance Acceptance Test

2.5 Replacement of Pump Assembly

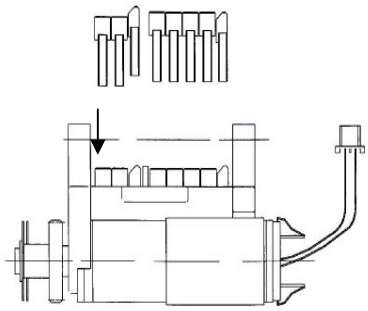
1. Separate the front and rear housing as described above.
2. Remove the pump door as described above.
3. Remove the flow direction label.
4. Remove the door hook screws (M2 x 2) and remove door hook.

5. Remove the 4 pumping block screws. These screws secure the pumping block to the front housing.

4 pumping block screws



6. Disconnect the motor connector on the motor PCB.
7. With the keypad facing up, observe the two metal hinge support features protruding from the front of the front housing assembly. Apply pressure evenly to the two hinge support features to push the motor block assembly out of the front housing assembly.
8. Install the old pumping fingers into the new pump block as illustrated below. Position fingers into slots in the pump block above cam. Ensure beveled side of fingers face encoder plate.



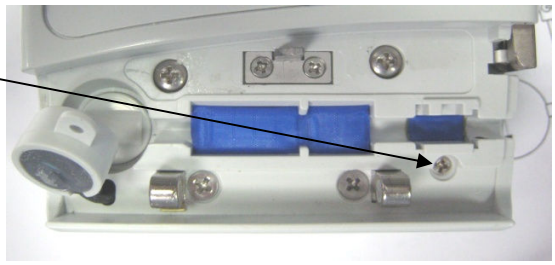
Position of Pumping Fingers in Pumping Block

9. Replace the motor block assembly by turning the front housing assembly so that the key pad is facing up.
10. Insert the new motor block assembly through the back side of the front housing so that the assembly is seated firmly against the inside of the front housing.
11. Reassemble in reverse order.
12. Perform Operational Checklist and Performance Acceptance Test.

3. Replacement of Pressure Sensor

1. Remove the pump door as described above.
2. Remove the pumping block assembly as described above.
3. Remove the 3 screws holding the motor PCB in place, carefully remove the Motor PCB.

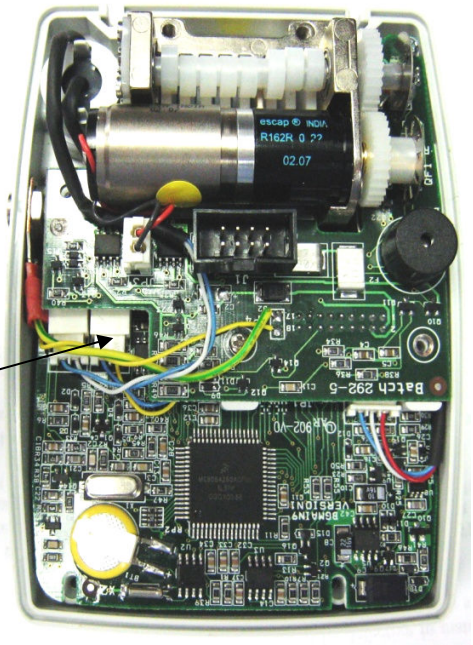
4. Remove the M2 screw from the inside of the pumping chamber located on the front housing near the pressure sensor.



5. Turn pump over and remove the self tapping screw holding the pressure sensor in place.
6. Pull the pressure sensor out of its recess.
7. Install new pressure sensor.
8. Reassemble in the reverse order.
9. Perform Operational Checklist and Performance Acceptance Test.

4. Replacement of Air Sensors

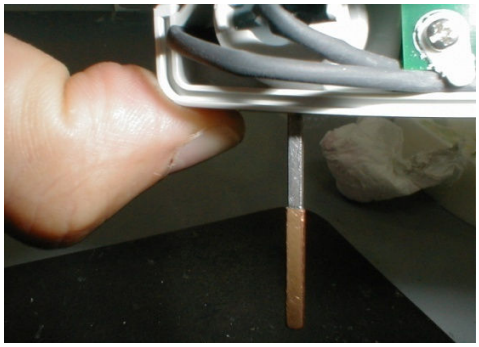
4.1 Front housing mounted air sensor:



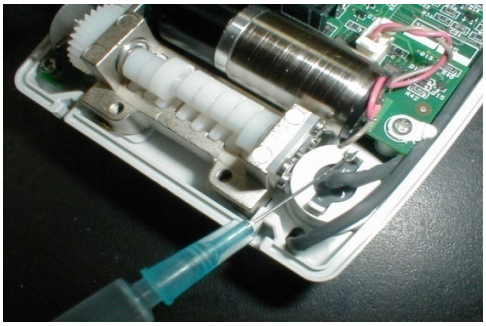
1. Separate the front and rear housing.
2. Disconnect the front housing mounted air sensor at connector JP4 on main PCB.

3. The air sensor is glued to the front housing. Using a screwdriver, apply enough pressure to the 'ears' on the back of the sensor to break them off, and then push the sensor out of its recess.

4. Replace the sensor with a new one. Use the Go No-Go gauge pins, (2.2 mm GO and 2.3 mm NO-GO) to ensure that the distance between the door mounted air sensor and the onboard air sensor is 2.3 mm.



5. Put a few drops of super glue on the sensor ‘ears’. Keep the ‘Go-No-Go’ gauge in between the sensors to ensure correct distance until the glue is dry.

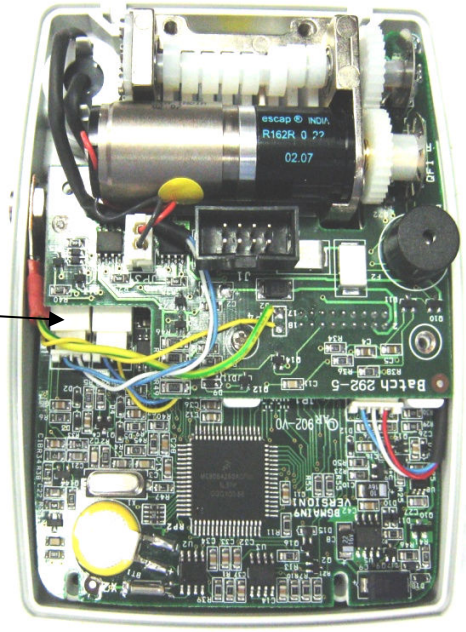


6. Reassemble in reverse order.
7. Perform the Operational Checklist Performance Acceptance Test.

4.2 Door Air Sensor:

1. Separate the front and rear housing.
2. Disconnect the door mounted air sensor at connector JP5.

Door Mounted Air sensor connector JP5



3. Remove the air sensor door screw.
4. Remove the sensor by using a sharp knife to remove the connector pins from the air sensor connector. Save this connector for later use.
5. Replace the sensor with a new one.
6. Insert the leads of the air sensor through the hole in the front housing.
7. Insert the blue and white lead connector pins into the air sensor connector housing. Insert pins into the connector housing so that when connected to the JP5 connector, the blue wire is inserted in the outside position, the white wire is inserted in the inside position.
8. Check that the distance is 2.3mm between the air sensors using the ‘Go-No-Go’ gauge and perform the air sensor testing procedure, as described on p. 19.
9. Perform Operational Checklist and Performance Acceptance Test.

5. Replacement of Pump Motor

1. Separate front and rear housings of the pump.
2. Remove the pump door as described above.
3. Remove pump assembly as described above.
4. Carefully place the pump assembly at a position in which the pumping fingers are facing upwards.
5. Apply a piece of insulation tape across the fingers to prevent them from falling out [if they do fall out, refer to diagram: "Position of Pumping Fingers in Pumping Block" for proper finger placement.]
6. Carefully place the pump assembly at a position in which the gear wheels are facing up.
7. Remove the nut, securing the single slotted encoder disc and remove the encoder.
8. Remove the retainer ring from the end of the motor and remove the encoder and motor gear.
9. Remove the 2 screws that hold the motor to the housing and remove motor.
10. Install a new motor. Refit the 2 screws using thread locking glue.
11. Reassemble in reverse order.
12. Perform Operational Checklist and Performance Acceptance Test.

5.1 Replacement of PC Boards – motor and main

1. Separate front and rear housings of the pump.
2. Remove the pump door as described above.
3. Remove pump assembly as described above.
4. Carefully place the pump assembly at a position in which the pumping fingers are facing upwards. Apply a piece of insulation tape across the fingers to stop them falling out (if they do fall out, refer to diagram: "Position of Pumping Fingers in Pumping Block" for proper finger placement).
5. Remove the 3 screws that are holding the motor PCB.
6. Remove the screw holding the main PCB to the front housing.
7. Remove PCBs.
8. Install a new motor PCB or a new main PCB.
9. Reassemble in reverse order.
10. Perform Operational Checklist and Performance Acceptance Test.

6. Replacement of LCD

1. Separate front and rear housings of the pump.
2. Remove the pump door as described above.
3. Remove the pump assembly as described above.
4. Carefully place the pump assembly at a position in which the pumping fingers are facing upwards.
5. Apply a piece of insulation tape across the fingers to keep them from falling out (if they do fall out, refer to diagram: "Position of Pumping Fingers in Pumping Block" for proper finger placement).
6. Remove the 3 screws that are holding the motor PCB.
7. Remove the screw holding the main PCB to the front housing.
8. Place the main PCB face up on the ESD mat so that the push buttons are facing up.
9. Rotate the main PCB so that one hand can be used to grip the LCD and the other can be used to cut the adhesive foam which holds the LCD to the main PCB.
10. Gently lift on the LCD and use the sharp knife to score the adhesive foam. After scoring the foam, disconnect the LCD from the main PCB by pulling the collar out of the LCD connector.
11. Remove all leftover adhesive foam.
12. Install a new LCD by plugging it into the connector and engaging the collar.
13. Place the LCD inside the white square that is printed on the Main PCB.
14. Reassemble the pump in reverse order.
15. Perform Operational Checklist and Performance Acceptance Test

7. Software Update and Replacement

Note: Before disassembling the pump, make sure to make note of the calibration settings, serial number, and date of production. Do not open pump without using the Electro Static Discharge (ESD) equipment. Failure to do so could result in damage to the internal circuitry of the pump.

Note: Software Updates will only be performed at the CME America Service Center in order to maintain device DHR.

1. Place the BodyGuard unit face down on the electro static discharge mat. Ensure that the ESD mat is free of debris and other objects that could cause scratches to the pump housing.
2. Using the #0 x 2-½ Phillips screwdriver remove the four screws from the back of the unit. Two of the screws are located at the top of the unit underneath the battery pack. The remaining screws are located at the bottom of the unit underneath the quality check label.
3. After removing the four screws from the back of the unit gently separate the back portion of the case from the front portion of the case. Set the back portion of the case aside and remove the screws from the case. Set the screws aside for later use.
4. Insert the battery into back portion of the case.
5. Using the five pin male to male wire, connect the PCB to the BodyGuard programming board by connecting the five pin connector wire to pin JP1.
6. Connect the RS-232 cable to the BodyGuard programming board and the com port on the back of the computer.
7. Carefully place the rear portion of the case onto the front portion of the case without disturbing the five pin wire connection.
8. Open the Prog08sz software. If the setup is connected properly the pump will begin to beep shortly after the programming software is opened.
9. Select the button labeled “Close COM Port”.
10. Set the correct port for the RS-232 cable by using to drop down menu labeled “Port”.
11. Change the baud rate to 8861 by using the drop down menu labeled “Baud”.
12. Check the box next to “IGNORE security failure and enter monitor mode”.
13. Select “Contact target with these settings”.
14. Select the program algorithm “908_az60a_highspeed.08p”. Make sure to select the program algorithm that was saved as a file not the algorithm that is included with the programming software.
15. Specify the S record by selecting it from the pick window. Use the proper file (i.e. USA35E13.s19).
16. Erase the module by selecting EM from the pick window. After the module has been erased reconnect with security.
17. Program the module by selecting PM from the pick window.
18. Select Quit from the pick window.
19. Disconnect the pump from the programming board.
20. Reassemble the pump and recalibrate.
21. Perform Operational Checklist and Performance Acceptance Test

8. Restore Software Default Settings

Note: Software default settings should only be restored before beginning the last Operational Checklist and Performance Acceptance Test after service has been completed.

Note: Complaint pumps will have software default settings restored after notification of complaint closure.

1. Power the pump on while pressing the INFO key to enter the Technician Menu.
2. Enter the appropriate Technician Code for the device.
3. Use the arrow keys to scroll to the option "Software Factory Setting".
4. Press the START/OK key.
5. Press the START/OK key to reset the software factory settings to default.
6. Select the "Restart Pump" option.
7. Press the START/OK key.
8. Verify factory default settings have been reset to default values in chart below. To assure default settings are restored for BodyGuard 545, and 575, check that protocol parameters in the "Select Protocol" option have been erased.
9. Add "Software Default Settings Restored" insert to pump packaging. This notifies customer that any desired customer programmed setting must be reprogrammed prior to use.
10. Perform Operational Checklist and Performance Acceptance Test

BodyGuard Pump Software Default Settings

BG 323		BG 545		BG 575	
Settings	**Default Value**	**Setting**	**Default Value**	**Setting**	**Default Value**
Pressure default	14 psi	Pulse Ox	Enabled	Pulse Ox	Enabled
Program	Continuous	Key stroke Volume	Lowest setting	Key stroke Volume	Lowest setting
Priming rate	Not adjustable	Occlusion Pressure	High 21 PSI	Occlusion Pressure	High 10 PSI
Max bolus volume	100 ml	Priming Volume	5 ml	Priming Volume	5 ml
Titration bolus	On	Priming Rate	400 ml/hr	Priming Rate	400 ml/hr
Bolus rate	600 ml/hr	Maximum CA Bolus	5 ml	Maximum CA Bolus	5 ml
Maximal rate	1200 ml/hr	Default Bolus Rate	0 ml/hr	Default Bolus Rate	0 ml/hr
KVO rate	0.0 ml/hr	Maximal Basal Rate	30 ml/hr	Maximal Basal Rate	5 ml/hr
Flow control	0 drops/ml	KVO Rate	0 ml/hr	KVO Rate	0 ml/hr
Set loading test	Off	Program Limits	OFF, volume	Program Limits	OFF, volume
Air bubble	0.3 ml	Air In Line Limit	0.5 ml	Air In Line Limit	0.5 ml
Store last program	Off	LED Indicator	ON	LED Indicator	ON
Operation led	On	Bolus Key	OFF	Bolus Key	OFF
Time option	Off	Titration Option	OFF	Titration Option	OFF
Delay before start	Off				

Service Center Recommended Parts

Service center recommended parts may be ordered from CME Distributor Recommended BodyGuard Parts List according to specific pump model.

Cleaning and Storage

Cleaning

Before connecting the pump to a patient, and periodically during use, clean the unit using a lint-free cloth lightly dampened with warm water and a 1:10 (10%) solution of bleach (bleach based disinfectant).

Warning: Always turn the pump off and remove the battery before cleaning.

Warning: Always unplug the charger from AC power before cleaning.

Caution: Do not clean the pump or charger with chemicals such as Xylene, Acetone or similar solvents. These chemicals can cause damage to plastic components. Use a lint-free cloth dampened with warm water and a mild detergent or disinfectant.

Caution: Do not soak or immerse any part of the pump or charger in water

Storage

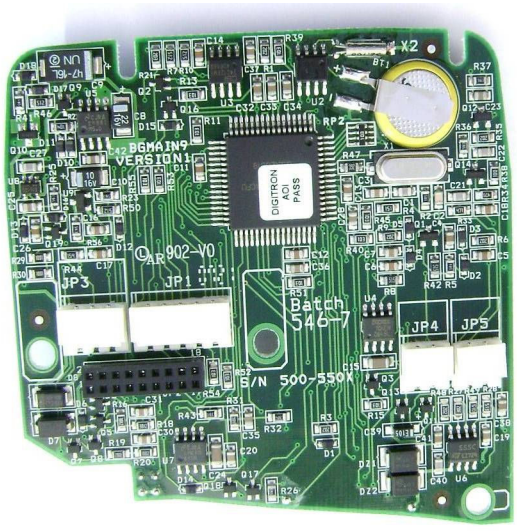
If the pump is to be stored for an extended period it should be cleaned and the battery fully charged. Store in a clean, dry atmosphere at room temperature and, if available, utilize the original packaging for protection.

Perform functional tests and ensure that battery is fully charged once every three months.

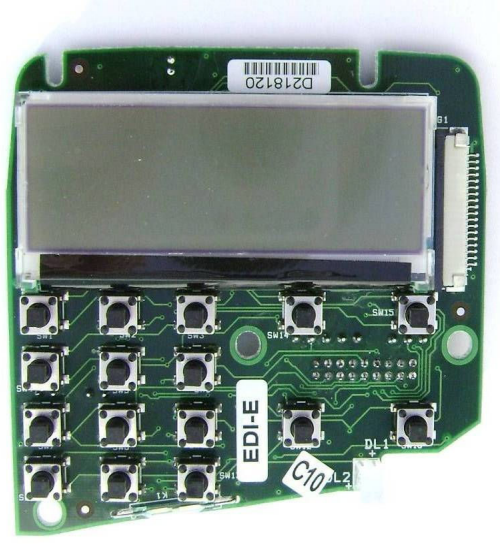
APPENDIX A

Front Housing (Rear View)

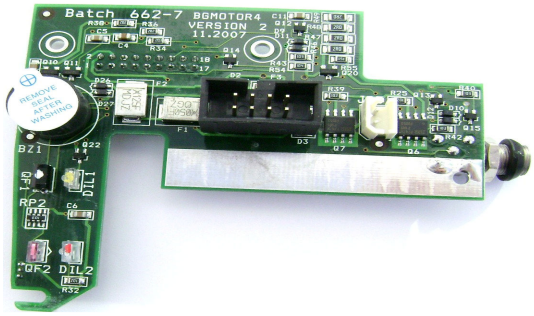
Rear Housing (Rear View)



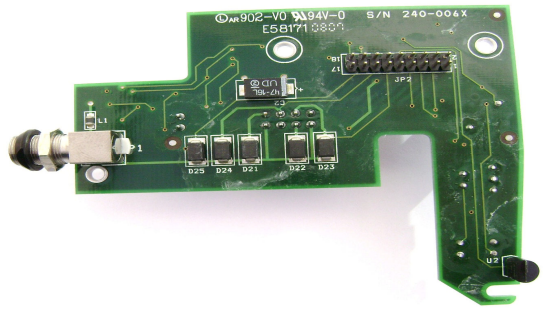
Main PCB (Rear View)



Main PCB (Front View with Display)



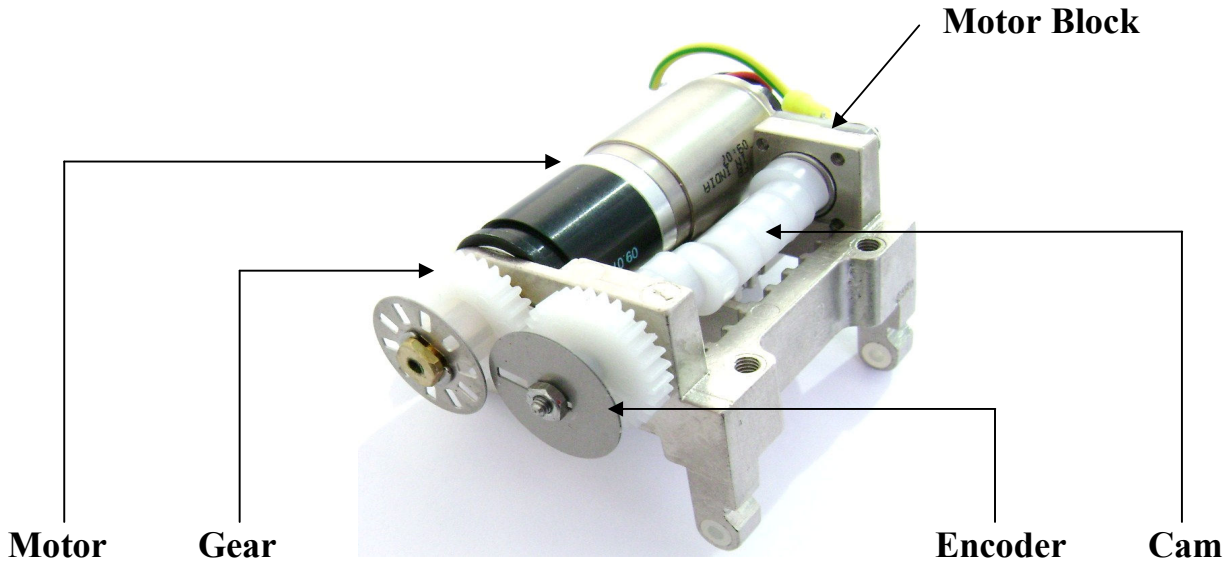
Motor PCB (Rear View)



Motor PCB (Front View)

Display (Rear View)

Display (Front View)



Motor Block Assembly